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EXAMINER

WEBB, WALTER E

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/524,996
Filing Date: February 18, 2005
Appellant(s): ASADA ET AL.

Richard S. Barth
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/30/2009 appealing from the Office action mailed 2/20/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 6,011,062	Schneider et al.	1-2000
US 5,556,848	Kimura et al.	9-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 6, 8, 10, 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al. (US 6,011,062), in view of Kimura et al. (US 5,556,848).

Schneider et al. teaches an ophthalmic solution comprising a prostaglandin at 0.001 to 0.005% at pH 6 +/- 0.2. (See col. 9, Example 2 (table).) Schneider teaches latanoprost among prostaglandins for the ophthalmic solution at column 5, line 57. Schneider et al. recognizes that prostaglandins are generally unstable and therefore teaches the use of polyethoxylated castor oils as a stabilizing agent (see abstract, col. 1, lines 13-14, and col. 2, lines 16-35).

Schneider et al. differs from the instant claims insofar as it does not teach adding ϵ -aminocaproic acid to its ophthalmic suspension.

Kimura et al. teaches an ophthalmic suspension containing difluprednate (see abstract). Kimura et al. teaches adding, preferably, acetates and ϵ -aminocaproic acid to its ophthalmic suspension since they suppress “formation of agglomerates, prevents lowering of pH, and provides a suspension superior in redispersability and stability” (see col. 3 lines 26-33). The reference teaches adding ϵ -aminocaproic acid in amounts of 0.01-2.0 w/v% relative to the entire suspension (see Id.) Additionally, Kimura teaches that polyoxyethylene castor oils are also useful for suppressing formation of agglomerates, preventing lowering of pH, and providing a suspension superior in redispersability and stability (see col. 3, lines 50-54). Kimura does not teach the use of latanoprost.

Because Schneider recognized the stability problems of prostaglandins, it would have been obvious to a person having ordinary skill in the art at the time of applicants invention to add a known stabilizing agent such as ϵ -aminocaproic acid at 0.01-2.0% w/v% to the composition of Schneider, motivated by the teaching of Kimura that ϵ -aminocaproic acid would suppress formation of agglomerates, prevent lowering of pH, and provide a suspension superior in redispersability and stability.

Established precedent holds, even a slight overlap in range establishes a prima facie case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Here, the amount of ϵ -aminocaproic acid, 0.01-2.0% w/v%, taught in Kimura et al. is certainly specific enough to reasonably suggest the instantly claimed percentages, and

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accordingly, it would have been obvious to have arrived at those percentages simply by following the general teachings of the reference.

(10) Response to Argument

Appellant describes the differences between ϵ -aminocaproic acid and castor oils and argues that the problems sought to be solved in Kimura et al. substantially differs from what is stabilized in the instant composition. However, the Examiner recognizes the differences between ϵ -aminocaproic acid and castor oils and reminds appellant that the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. MPEP 2144. The prior art recognized the need for a storage stable prostaglandin composition. Adding ϵ -aminocaproic acid would have been obvious since it is known in the prior art as useful for suppressing formation of agglomerates, preventing lowering of pH, and providing a suspension superior in redispersability and stability. Kimura et al. teaches the use of a different active agent, but the artisan would reasonably expect ϵ -aminocaproic acid to provide the same stability in the ophthalmic suspension of Schneider et al., given its generic recitation in the reference, and the fact that ϵ -aminocaproic acid is listed among other ophthalmic components taught in Schneider such as castor oils and sodium acetate (see Schneider et al. at col. 8, lines 1-15). Moreover, sodium acetate would reasonably suffice as an

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equivalent to ϵ -aminocaproic acid, and thus provide a further basis for prima facie obviousness since it is generally obvious to replace one component for another equivalent component (see MPEP 2144.06).

The Examiner acknowledges that the increased stability has apparently been demonstrated, as argued. However, the increased stability is viewed as being expected insofar as ϵ -aminocaproic is recognized in the art as a stabilizing agent for ophthalmic formulations. Appellant's results in regard to pH, Table 1, are also not unexpected since specific embodiments of the composition of Schneider have a pH of 5.

The Examiner also acknowledges that the percentages between formulations 1-8 are very close when stored at 50°C for eight weeks, e.g. formulation 2 containing PEG 400 shows 88.8%, while formulation 8 containing the ϵ -aminocaproic acid shows 93.1%. The differences were much greater where the formulations were stored 80°C for four weeks, e.g. formulation 2 containing PEG 400 shows 25.9%, while formulation 8 containing the ϵ -aminocaproic acid shows 51.8%. However, appellant provides no explanation for the significance of the percentages in regard to stability. It is also unclear how the storage time and temperatures relate to storage at room temperature generally.

Even if, appellant's data showed an unexpected result, the instant claims are not commensurate in scope with these results. Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support" (see MPEP 716.02(d).) In other words, the

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showing of unexpected results must be reviewed to see if the results occur over the entire claimed range (Id.). Appellant's claims are drawn to storage at room temperature, which is commonly between 20°C to 25°C, and do not recite time of storage. The results are also inconsistent in regard to pH, since formulations 1-8 are shown to have a pH of 7, while the instant claims 12, 14 and 16 are limited to a pH of 5.0 to 6.25. The other claims are not limited whatsoever in regard to pH. The Examiner raised these concerns earlier in the prosecution, but Appellant argued that it was not necessary to amend claims to recite the time period for the stability or even the degree of stability (see Miscellaneous Incoming letter filed 4/17/2008).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Walter E. Webb

/Walter E Webb/

Examiner, Art Unit 1612

Conferees:

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